

REMARKS

Entry of this Amendment is proper under 37 C.F.R. § 1.114, as amendments and arguments are submitted.

1. Status of the Claims

Claims 1-6, 8-11, and 20-35 stand pending. Claims 33-35 stand withdrawn. Claims 1-6, 8-11, and 20-32 stand rejected.

After entry of the above amendments, claims 6-24 and 28-35 stand cancelled, including claims 33-35, which had been withdrawn as drawn to a separate invention.

Applicants have amended Claim 1 and introduced new claims 36-39. The new claims are supported by at least the original claims as well as Examples 2 and 4 and Tables 2 and 3. Applicants do not believe that the amendments add subject matter that is unsupported in the Specification as filed. Additionally, the amendment of the type of resin column being a styrene-divinylbenzene resin column is supported in the specification at least for example at page 11, lines 19-20 and in the Examples. Accordingly, no prohibited new matter is introduced by the entry of the amendments.

Claims 6-24 and 28-35 have been cancelled without prejudice to, or disclaimer of, the cancelled subject matter. Applicants reserve the right to file a continuation or divisional application on any subject matter canceled by way of amendments.

2. Information Disclosure Statement

Applicants note with appreciation the acknowledgement of the Information Disclosure Statement filed February 8, 2008.

3. Withdrawal of the Claims

The Office withdraws claims 33-35 from consideration as being directed to a non-elected invention. Specifically, the Office alleges that the previously submitted claims 33-35 are distinct species from the originally claims for being directed at pharmaceutical compositions "comprising an *SDS*-rich product." Page 2, Office Action (emphasis added). The present application only describes secoisolariciresinol diglycoside (*SDG*); therefore, Applicants assume the Office means "an *SDG*-rich product."

Applicants submit that the Office has not adduced a proper basis for why claims 33-35 cannot be examined with the present invention. No explanation as to separate class of invention is set forth and no explanation of burden. Additionally, the claims depend from claims presently under examination and are thus linked.

Nevertheless, in order to expedite examination, Applicants have canceled claims 33-35.

4. Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

The Office rejects claims 1-5 and 25-27 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges that claims 1-5 and 25-27 contain subject matter that was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the claimed invention at the time the application was filed.

Applicants traverse the rejection. As long as enough detail in the specification has been set forth to allow an ordinarily skilled in the art (1) to understand what is claimed and (2) to recognize that the named inventor(s) invented what is claimed, the written description of 35 U.S.C. § 112, first paragraph, has been satisfied. *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 921, 69 U.S.P.Q.2d 1886, 1896 (Fed. Cir. 2004). Moreover, “a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art.” *Koito Mfg. Co. v. Turn-Key-Tech LLC*, 381 F.3d 1142, 1156, 72 U.S.P.Q.2d 1190, 1200 (Fed. Cir. 2004). Here, the Office issues the rejection without applying the correct legal standard.

“washing the column with 0-10% alcohol (v/v)” in Claim 1

The Office alleges that the Specification does not disclose a limitation in previously presented claim 1, i.e. “washing the column with 0-10% alcohol (v/v).” Applicants traverse.

In this type of purification/enrichment through column chromatography, the meaning of “washing” and “eluting” would be apparent. *Ipsis verbis* support is not the legal requirement. See e.g., *Ex parte Holt*, 19 U.S.P.Q.2d 1211, 1213 (PBAI 1991). Both washing and eluting are steps involved in such column purification/enrichment processes. In pilot experiments to optimize the purification/enrichment conditions, solutions of different

compositions are initially used for "eluting." At this stage, each flow-through is collected and analyzed to determine a range that is most efficient for purification/enrichment.

In at least Examples 3-4 of the Specification, alcohol of 0% (water), 10%, 15%, 20%, and 40% has been used in the experiment to purify SDG. Applicants present findings that (1) SDG is barely washed out by alcohol of 10% or less, and (2) SDG is enriched with alcohol of 15-40%. *See e.g.*, page 17, line 20 to page 28, line 24, and Table 3 of the Specification. Based on at least these descriptions, the ranges of alcohol for washing and eluting are described in the specification and thereby support the claims.

Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

"eluting the column with 15 to 40% alcohol (v/v)" in Claim 1

The Office admits that Example 4 of the Specification discloses the elution with 10%, 15%, 20%, and 40% of alcohol (v/v). Nevertheless, the Office alleges that the Specification fails to disclose the 15-40% range, because of the absence of the disclosure of 25% or 30%. Office Action, page 2, last para.

Applicants traverse. To satisfy the written description requirement, neither the statute nor the case law requires the Applicants to disclose each individual concentration within the range of 15-40%. Such a range theoretically contains infinite discrete concentrations, which are impossible to be disclosed individually in any application. Here, the Applicants have presented examples over the claimed range. Additionally, the original claims (*see, e.g.* original claim 4 which describes 30-100% v/v) provide another range. There is sufficient support in the specification for that which is presently claimed.

Accordingly, Applicants respectfully request the withdrawal of the rejection and allowance of the claims.

"ethanol" in Claim 26

The Office alleges that the Specification does not disclose washing with ethanol as recited in claim 26. Office Action, page 2, last para.

Applicants traverse. As mention above, the meaning of "washing" or "eluting" should not be interpreted literally in the present application. Applicants direct the Office to page 18, lines 13-14 of the Specification:

SDG was scarcely eluted with *10% ethanol*.

(emphasis added). After determining that ethanol of 10% ethanol or less scarcely eluted SDG, it was determined that 10% or less ethanol was appropriate for washing. In view of the above arguments, Applicants respectfully request the withdrawal of the rejection.

Applicants additionally point out to the Office on page 18, lines 16-19 that the specification further teaches that "elution with 40% ethanol recovered 2.9 g of SDG at a purity of 11.8%. No more SDG was eluted even when the ethanol concentration was further increased." The specification additionally states "[f]or Example, SDG is preferably eluted at an alcohol concentration of 15% or more" on page 18, lines 21-22. These further descriptions further evince that ranges of alcohol for washing of 0-10% are utilized and for eluting, the ranges of 15% to 40% are utilized.

In view of the above evidence and arguments, the rejection should be withdrawn and the claims allowed.

5. Rejection of the Claim under 35 U.S.C. § 102(e)

The Office rejects claims 6 and 28-32 under 35 U.S.C. § 102(e) as allegedly being anticipated by Pihlava et al. (WO 02/062812A1) [hereinafter "Pihlava"].

Without acquiescing as to the merits of the rejection, Applicants have canceled claims 6 and 28-32, thereby mooted the rejection. The rejection can be withdrawn.

6. Rejection of the Claim under 35 U.S.C. § 103(a)

6.1 Rejection over Pihlava

Claims 1-5 and 25-27 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pihlava. The Office alleges that Pihlava disclose that:

- 1) an SDG-rich product is extracted from the defatted and crushed flaxseed;
- 2) the defatted flaxseed is extracted with sodium hydroxide-methanol;
- 3) the SDG can be enriched by chromatography, with C18 material packed in a flash chromatography system;
- 4) the SDG can be enriched by washing the loaded column with various alcohol-water mixtures; and

5) the SDG can be eluted with 40% methanol.

The Office admits that Pihlava does not disclose:

- 1) the concentration of alcohol used for washing as in claim 1;
- 2) the concentration of alcohol as in claims 4 and 25; and
- 3) the temperature as in claims 27.

The Office alleges that both the temperature and alcohol concentrations are result-effective variables that can be determined by a skilled artisan through routine experimentation. The Office thus concludes that claims 1-5 and 25-27 are obvious over Pihlava.

Applicants traverse. Pihlava discloses isolating and purifying SDG from flaxseed using reverse-phase partition chromatography, which is known in the art as appropriate as a small scale purification technique, not a large scale technique. The current claims utilize adsorption chromatography. Applicants have amended the claims to recite a specific type of resin chromatography. Adsorption chromatography methods are appropriate for large-scale industrial purification techniques.

The two techniques are based on different principles for different purposes and are not interchangeable for the same problem. For example, adsorption chromatography is less advantageous in terms of purification efficacy than partition chromatography in separating a mixture based on structural differences of substances or in separating a mixture based on structural differences of substances or in separating a mixture based on size of substances. In that regard, Applicants provide an English translation of the paper entitled "Thin-Layer Chromatography – Basis and Applications." [Attached]

For the instant claims, the mixture extracted with a basic alcohol from plant material that contains SDG is a mixture comprising different structural substances of difference sizes. Such a mixture would not have a reasonable expectation of purification efficiency using the adsorption chromatography method. However, it was both successful and efficacious and it turned in to a relatively simple process. Identifying a simple, efficacious and successful method of purifying SDG had been sought after.

The reversed-phase partition chromatography employed in Pihlava separates SDG from other substances by differences in partition coefficient of the substances resulting from

their differences in partition coefficient of the substances resulting from their differences in hydrophobic interaction with the C18-modified silica particle column. Here, SDG is separated from other substances by the differences in their retention times. To distinguish the differences in the retention times of each substance, the amount of the starting sample loaded to a column must remain small. Thus, Pihlava's teaching cannot be scaled up for large scale purification. Pihlava's method further requires several drying steps. Pihlava further requires repeated column purification steps. *See e.g.*, page 6, lines 10-22 and 24-33 of Pihlava. There is no teaching or suggestion in Pihlava on how these steps could be removed and still efficaciously purify SDG. Additionally, there is no teaching or suggestion to instead use adsorption chromatography *and* remove the other repeated purification steps and drying steps of Pihlava. Additionally, Pihlava also does not teach the recited resin column.

The adsorption chromatography of the current claims separate SDG from other substances by trapping it to the HP20 resin. SDG is then desorbed from the resin using alcohol. Adsorption chromatography differs from partition chromatography, as the former includes a desorbing step that removes the trapped SDG from the resin by the alcohol wash. At least one advantage of adsorption chromatography is its ability to process a far larger amount of a starting sample than can be achieved using partition chromatography. This particular advantage lends itself to industrial application. The processing step of the alcohol washes is what allows the claimed method to provide a sufficient amount of SDG in quality and quantity in an efficacious fashion.

In Pihlava, at best only 100 g of defatted powder of flaxseed can be processed. Yet in the instant case at least 1 kg of flax cake is processed. *See e.g.*, Examples 1 and 4 of the specification.

The Office further argues that Pihlava discloses that SDG is eluted with 650 ml of 40% methanol. The Office thus concludes it would have been obvious. This conclusion is unreasonable and unfounded. The solvent used in chromatography depends on the chromatography technique used. The technique used in Pihlava differs from that of the present claims. Pihlava at best only teaches optimizing the alcohol content for reverse-phase partition chromatography for small scale purification.

As discussed in part above, on page 18, lines 16-19 of the specification, Applicants discuss that elution with 40% ethanol recovered 2.9 g of SDG at a purity of 11.8%. No more SDG was eluted, even when using ethanol concentrations in excess of 40%. Thus,

Applicants found that about 40% ethanol is the concentration suited for SDG recovery. The findings are significantly meaningful in recovering SDG by the chromatography technique recited herein, that is a large scale chromatography technique distinct from that of Pihlava.

For at least these reasons, Applicants submit that Pihlava fails to render claims -5 and 25-27 obvious. Accordingly, the rejection should be withdrawn and the claims allowed.

6.2 Rejection over Pihlava in view of Empire

Claims 8-11 and 20-24 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pihlava in view of Empire et al (U.S. Patent No. 6,391,308) [hereinafter "Empire"].

Without acquiescing as to the merits of the rejection, the claims have been cancelled thereby mooting the rejection. The rejection can thus be withdrawn.

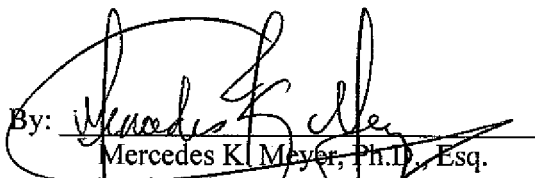
CONCLUSION

In conclusion, this is believed to be in full response to the outstanding final Office Action. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience.

Should any outstanding fees be owed or overpayments credited, the Commissioner is invited to charge or credit Deposit Account No. 50-0573. The Office is authorized to charge the Deposit Account for a Notice of Appeal should a Notice of Appeal be necessary to maintain pendency of the application.

Respectfully submitted,
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